



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,483	06/01/2001	Norimasa Okuda	04853.0072	1041

22852 7590 11/14/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 11/14/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,483

Applicant(s)

OKUDA ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-9, 11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 11, 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-3, 7-9, 11, and 13-19 are pending.

Claims 1-3, 7-9, 11, and 13-19 have been rejected.

Claim Rejections-35 USC 112

1. Applicants' argument filed 8/12/2003 have been fully considered but they are not persuasive.

The rejection of Claims 1-3, 7-9, 11, and 13-19 under 35 USC 112, first paragraph, has been maintained due to applicants' failure to change in the amendment.

The rejection of Claim 17 under 35 USC 112, second paragraph, has been withdrawn due to the modification made in the amendment.

Claim Rejections-35 USC 102

Rejection of claims 1-3, 7-9, 11, 13, 14, 17, and 18 under 35 U.S.C. 102(b) as being anticipated clearly by Effenberger et al (Tetrahedron Letters p. 2608) has been changed to rejection of claims 1-3, 7-9, 11, 13, 14, 17, and 18 under 35 U.S.C. 103(a) as being unpatentable over Effenberger et al (Tetrahedron Letters p. 2605- 2608) in view of Kawabe et al (U.S. 5,763,52).

Claim Rejections-35 USC 103

Rejection of claims 15-16 under 35 U.S.C. 103(a) as being unpatentable over Effenberger et al (Tetrahedron Letters p. 2605- 2608) in view of Kawabe et al (U.S. 5,763,52).

Rejection of Claim 19 under 35 U.S.C. 103(a) as being unpatentable over Flege et al (US. 4,218,380).

The rejection of claims 15-16 under 35 U.S.C. 103(a) as being unpatentable over Bock et al (U.S. 4,177,342) is maintained for the reasons of the record in paper no. 17.

The rejection of Claim 19 under 35 U.S.C. 103(a) as being unpatentable over Flege et al (US. 4,218,380) is maintained for the reasons of the record in paper no. 17.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 7-9, 11, 13, 14, 17, and 18 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Effenberger et al (Tetrahedron Letters p. 2605- 2608) in view of Kawabe et al (U.S. 5,763,52).

Effenberger et al discloses a method of producing (R)- α -hydroxy - α -methyl-heptanoic acid in the following steps of:

- A. hydrolyzing a (R)- α -hydroxy - α -methyl-heptane nitrile (1.75mmol) in the presence of conc. hydrochloric acid (5ml)(56.5mmol) with heating under reflux;
- B. extracting the mixture containing water with diethyl ether, and

Art Unit: 1625

C. crystallizing the desired product by filtration and concentration

(see page 2608, # 15).

However, the instant invention differs from Effenberger et al in that the aromatic solvents are used in the process.

Kawabe et al teaches a process for producing a carboxylic acid by hydrolyzing a nitrile compound (see col. 1, lines 13-15), such as an alpha-cyanohydrin (see col. 5, lines 31-50), in the presence of an acidic catalyst and a hydrocarbon solvent, such as hexane, benzene, or xylene (see col. 14, lines 41-44).

Effenberger et al expressly teaches the method of producing (R)- α -hydroxy - α -methyl-heptanoic acid by hydrolyzing a (R)- α -hydroxy - α -methyl-heptane nitrile in the presence of hydrochloric acid and the hexane solvent. Also, Kawabe et al does disclose the process for producing the carboxylic acid by hydrolyzing the the alpha-cyanohydrin in the presence of the acidic catalyst and the hydrocarbon solvent, such as hexane, benzene, or xylene. Both have shared a common process of producing an alpha-hydroxycarboxylic acid with similar conditions: the acidic catalyst and the hydrocarbon solvent. Furthermore, Kawabe et al does point out that there is no difference as to the use of either hexane or benzene during the process of producing the desired product alpha-hydroxycarboxylic acid.

Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use the Kawabe et al benzene solvent in the Effenberger et al process as an alternative to hexane. This is because the skilled artisan in the art would expect a similar success as in the case of using the benzene solvent during the process.

Response to Applicants' Argument

1. Effenberger does not use the n-hexane in the hydrolyzation process;
2. Kawabe discusses a hydrocarbon solvent in the context of an amide extracting step, not a hydrolyzing step;
3. the Examiner has not explained how Fiedge renders obvious an optically active chloromandelic acid with a packing density greater than 0.50.

First, with respect to the first and the second arguments, the Examiner has noted applicants' argument. However, according to the Effenberger reference, there is a generic teaching of the hydrocarbon solvent; especially, as we look into the passage related to how the nitrile starting material is obtained in the presence of an organic solvent (see page 2605 , lines 15-16), which can be a hydrocarbon solvent. Therefore, it is possible to conduct the hydrolyzation process in the presence of the hydrocarbon solvent like n-hexane.

Second, regarding the third argument, the Examiner has noted applicants' argument. However, Concerning the packing density of the compound , this is not

Art Unit: 1625

related to the novelty of the instant invention, but rather is naturally obtained as a unique physical property for evaluating the compound. Furthermore, the selection of density of the compound is not a patentable modification in the absence of unexpected results. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to obtain the claimed density of the compound as part of routinely evaluating physical characteristics for the known compound in the process of the storage.

Conclusion

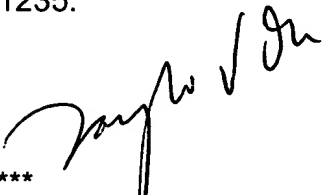
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



November 2, 2003


D. MARGARET SEAMAN
PRIMARY EXAMINER